U.S. House of Representatives
Committee on Transportation and Infrastructure
Washington, DC 20515

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April 21, 2009

SUMMARY OF SUBJECT MATTER

TO: Members of the Subcommittee on Aviation

FROM: Subcommittee on Aviation Staff

SUBJECT: Hearing on "Oversight of Helicopter Medical Services"

PURPOSE OF HEARING

On Wednesday, April 22, 2009, at 10:00 a.m., in room 2167 Rayburn House Office Building, the Subcommittee on Aviation will meet to receive testimony regarding Oversight of Helicopter Medical Services. The hearing will explore two issues: (1) helicopter emergency medical services (HEMS) safety and (2) state regulation of HEMS.

BACKGROUND

Medical research in the 1970s showed that patient transport is most critical within one hour for serious injuries.[1] Many studies have demonstrated that patients have improved recovery times and reductions in mortality rates when HEMS are utilized, especially in the case of cardiac arrest, stroke, and traumatic brain injury.[2] HEMS provide access for 81.4 million Americans who otherwise would not be able to reach a trauma center within an hour.[3] Helicopter air ambulances[4] conduct hospital inter-facility transfers (54 percent of operations), pickup patients at an accident scene, such

[1] R. Adams Cowley, *A Total Emergency Medical System for the State of Maryland*, 24 Maryland State Medical Journal 41-42 (1975).
[2] The Foundation for Air Medical Research and Education (FARE), Air Medicine: Accessing the Future of Health Care 4 (2006).
[3] Charles Branas, et al., *Access to Trauma Centers in the United States*, 293 Journal of the American Medical Assoc. 2626-2623 (2005).
[4] The terms helicopter air ambulance and HEMS will be used interchangeably. This memo will focus on HEMS in emergency medicine; however, HEMS operators also support firefighting and disaster response, planning, and management.

as a car collision on a roadway (33 percent), conduct training flights, and reposition back to the helicopter base.[5] U.S. operators generally operate with a single pilot, a nurse and a paramedic. Between December 2007 and October 2008, there were 13 HEMS accidents, resulting in 35 fatalities—the greatest number of accidents in any 11-month period. Between 1998 and 2008, there were 146 HEMS accidents with 131 fatalities.[6] Given the number of emergency medical services (EMS) helicopters, the Congressional Research Service (CRS) estimated in May 2006 that 1 in 50 helicopter air ambulances had been involved in a crash during the previous 3 years.[7] The Federal Aviation Administration (FAA) estimates the fatal accident rate from 2002 to 2008 was 1.18 per 100,000 flight hours.[8]

The HEMS industry is typically characterized as follows:[9]

- **Hospital-based (also known as traditional) operators**: A hospital provides the medical services and staff, and contracts with an aviation service provider (which holds an FAA operating certificate) for pilots, mechanics, and aircraft.

- **Independent (also known as stand-alone or community-based) operators**: An independent operator sets up a base in a community and serves various facilities and localities. The operator holds the FAA operating certificate and employs medical and flight crews (or contracts for those services).

The HEMS industry has grown dramatically over the past three decades, with the greatest expansion in recent years, primarily with independent operators. Between 2003 and 2005, the number of helicopter air ambulances increased from 545 to 753;[10] today the number is about 850.[11] The industry's growth is attributed to changes in the U.S. healthcare system, including changes in Medicare fee reimbursement starting in 2002.[12] The old Medicare structure's rates did not fully reimburse operators for the cost of helicopter transport, whereas the new structure reimburses operators at about 100 percent. This new reimbursement structure incentivized independent operators to enter the market due to the potential for more certain and higher income. Operators are only eligible for reimbursement from a flight if they actually transport a patient.

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[5] Government Accountability Office (GAO), Improved Data Collection Needed for Effective Oversight of Air Ambulance Industry 5 (2007). Data includes fixed-wing emergency medical aircraft.

[6] Witness Presentation by Dr. Ira Blumen, National Transportation Safety Board (NTSB), Public Hearing in the Matter of the Issues on Emergency Medical Services Helicopter Operational Safety at 21 (Feb. 3, 2009) (No. SA-530).

[7] Bart Elias, CRS, The Safety of Air Ambulances (2006).

[8] FAA, Briefing to Congressional Staff (Oct. 24, 2008). FAA does not require HEMS operators flying under 14 C.F.R. § 135 or § 91 to report activity data; therefore, this rate is an estimate. In 2003, the NTSB recommended that FAA require nonscheduled part 135 operators to report activity data on an annual basis. *See* NTSB Recommendation A-03-037.

[9] Pubic service entities (e.g. State Police, Sheriff's Department, or the military, etc.) also conduct HEMS operations in selected areas. "Subscription services" are another type of HEMS operation where the customer contracts with an aviation service provider to provide air transportation to a medical facility if needed.

[10] NTSB, Special Investigations Report on Emergency Medical Services Operations (2006).

[11] John Allen, Director, Flight Standards Service, FAA Helicopter Safety Initiatives, Briefing to Congressional staff (Mar. 20, 2009).

[12] *See* the Balanced Budget Act of 1997, Pub. L. No. 105-33 § 4531(b), 111 Stat. 451 (42 U.S.C. 1395m(l)) (1997).

I. Safety

Beginning in 1988, the NTSB issued many safety recommendations regarding HEMS.[13] Following a string of deadly accidents in 2008, the NTSB added its four 2006 safety recommendations to its "Most Wanted List." In February 2008, the NTSB held a 4-day public hearing on "Safety of HEMS Operations."

An analysis by the Air Medical Physician Association demonstrates that the following factors contribute to HEMS accidents: human error; communications problems between pilots and weather services, other pilots, HEMS dispatchers, scene (police, firefighters, etc.) or hospital personnel, and air traffic control; time- and exigency-related pressures; distractions, such as equipment problems, radio monitoring, poor visibility; workload or flight/duty length; loss of situational awareness;[14] failure to obtain a weather briefing; environmental issues, such as mountainous operations, nighttime or reduced visibility conditions; aircraft malfunction issues; inadvertent encounter with power lines; landing zone problems, including congestion and obstacles; pressure to accept a flight; and maintenance issues.[15]

Other issues affecting the HEMS industry are "helicopter shopping" and "call jumping." According to the FAA, helicopter shopping "refers to the practice of [an EMS dispatcher] calling, in sequence, various operators until an operator agrees to take a flight assignment, without sharing with subsequent operators the reasons the flight was declined by the previously called operators."[16] This can be a dangerous practice if the flight assignment was turned down for reasons that could affect another responding operator, such as poor weather and visibility at an accident scene. In a 2006 letter to State EMS Directors, the FAA recommended that EMS dispatchers disclose to other operators the reason for one operator turning down an assignment.[17] Call jumping is when a HEMS operator "self-dispatches" to a scene without prior request or when multiple operators are dispatched to a scene. In scene response situations, the decision to utilize a helicopter air ambulance rests with the on-scene first responders. Since the airspace which helicopters operate in is uncontrolled, this can be dangerous and could lead to a mid-air collision between multiple helicopters.[18]

FAA has issued many advisory documents to HEMS operators to improve safety, and recently issued some operating requirements. It is reported that the HEMS industry is working to

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[13] *See* NTSB Recommendations A-88-1 through A-88-19 (Feb. 29, 1998); A-06-12 through A-06-15 (Jan. 25, 2006) (Added to the NTSB's "Most Wanted List" for 2009); A-07-111 and A-07-112 (Dec. 21, 2007).

[14] Situational awareness is defined as "the accurate perception and understanding of all the factors and conditions going on around you. In aviation, this deals with...the pilot, the aircraft, the environment, and the type of operation that comprise any given aviation situation." Dr. Ira Blumen, Air Medical Physician Handbook, A Safety Review and Risk Assessment in Air Medical Transport (Nov. 2002), at 52.

[15] *Id.* at 14-16.

[16] James J. Ballough, Former Director, Fight Standards Service, FAA, Letter to State EMS Directors (2006).

[17] *Id.*

[18] GAO, *supra* note 5, at 20. Helicopters often operate in Class G uncontrolled airspace, which is below the altitude minimums required to be controlled by air traffic control (ATC). Most of the airspace up to 1,200 feet above ground level is uncontrolled. However, even in these operations, a helicopter pilot may be in communication with ATC if landing or departing from an airport. Operators may work with FAA to develop specific routes for landing/taking off from a base in order to standardize routing, enhance safety, and decrease a potential noise impact. In addition, some operators have developed Global Positioning Systems (GPS) approaches to regularly-used bases or hospital pads.

improve safety and has voluntarily implemented some of FAA's guidance. Despite this, 2008 was the deadliest year on record.

A. Operating Regulations

HEMS operations fall under one of two FAA regulatory regimes—14 Code of Federal Regulations (C.F.R.) part 91 or part 135. Part 91 sets basic operating requirements for any user of the national airspace. Part 135 is a stricter set of regulatory requirements, imposed when a passenger is paying for the flight; it is designed for commuter and on-demand air transportation. In the HEMS environment, the "passenger" is the patient. The strictest set of operating regulations is part 121, which is used by major commercial air carriers. HEMS operators are required to comply, at minimum, with part 91 if no patient is on the aircraft, and part 135 when a patient is onboard.

The major difference between part 91 and part 135 is weather and visibility minimums, which is the distance that the pilot can see, and the distance between the helicopter and the clouds. Under part 91, the weather and visibility minimums are lower than under part 135. For example, under part 91, the pilot must only operate clear of clouds and must be able to see any air traffic or obstruction to avoid a collision.[19] In contrast, under part 135, a pilot must be at least 1,000 feet from clouds or have 2 miles of visibility; and must have a visual ground reference during the day and a visual surface light reference at night.[20] In January 2009, FAA issued a regulatory requirement (through its operations specifications, or "OpsSpec," system) that raised the weather and visibility minimums to, or above, part 135 even when a HEMS operator is flying under part 91.[21] The FAA made this change so that the medical personnel onboard the helicopter air ambulance would be flown under the same weather minimums as a patient.

Under both sets of regulations, pilots fly according visual flight rules (VFR) or instrument flight rules (IFR). VFR means that the pilot relies solely on his/her visual cues to control the helicopter. VFR weather and visibility minimums are stricter than IFR minimums. IFR requires the pilot to use instruments to navigate the helicopter in lower weather and visibility conditions. The GAO noted, "some industry trade organizations consider flights that utilize instruments to be much safer than the flights that rely solely on visual cues."[22]

Although operating according to IFR is considered to be safer, pilots cannot always fly under IFR because it requires a low-altitude infrastructure that is not always available in most locations.[23] Also, the aircraft and pilots must be certified with specific avionics and training, respectively, to fly under IFR.[24]

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[19] 14 C.F.R. § 91.155 (2008).
[20] 14 C.F.R. §§ 135.205, 135.207 (2008).
[21] FAA, Operations Specification A021, [HEMS] Operations (Jan. 23, 2009).
[22] GAO, *supra* note 5, at 32-33.
[23] Low-altitude infrastructure would include GPS, Wide Area Augmentation System (WAAS), and Automatic Dependent Surveillance-Broadcast (ADS-B), and the development of point-in-space approach procedures. The FAA Reauthorization Act of 2009, H.R. 915, includes a provision that reauthorizes funding for the development and maintenance of approach procedures for heliports that support all-weather, emergency services.
[24] *See* 14 C.F.R. §§ 135.163, 135.243 (2008).

B. Flight Dispatch

Emergency ground responders, hospital physicians, or 911 dispatchers are charged with determining whether or not air transportation is necessary for patient transport based on specific patient coordination criteria.[25] Once that decision is made, that person will call a HEMS provider's communications center to see if it can accept the flight request. The communications center typically has an operations control specialist "who generally works for or under contract to an aviation operator and has specific aviation knowledge, including the effects of weather . . . and operational needs of the flight"[26] and then contacts the pilot in command to notify him/her of the flight request. Then, the pilot will use all available information, including weather, route, and in-flight risks, to determine if the flight can be made.

Many operators are now using a flight risk evaluation to determine the risks of taking the flight. A flight risk evaluation is a risk management tool in which a pilot and a manger, flight dispatcher, or another flight crewmember assess all risks associated with deciding to dispatch, including adverse weather and visibility conditions; terrain on the route; the optimum flight plan; technologies that aid in managing risk; flight crew performance; and organizational environment. In 2005, the FAA issued guidance that recommended operators use a risk assessment evaluation and included a checklist and a risk matrix to use as templates.[27]

According to the NTSB, typically the risk evaluation results in one the following determinations: (1) safe, the flight is launched without further concern; (2) risks are present, and the pilot needs to consider and take appropriate risk mitigation activities (e.g., use of certain technology if trained and present, or operate only under IFR); (3) significant risk is present and the pilot must consult with, and obtain permission from, the operator's chief pilot or director of operations; (4) risk is too high, and the pilot must decline to take the flight. If the pilot determines that the flight cannot be made, he/she will communicate this with the operations control specialist, who then notifies the requesting party.

In 2006, the NTSB conducted a special investigation and found that none of the operators involved in HEMS accidents studied had a flight risk evaluation program. NTSB issued recommendations to require EMS operators to use formalized dispatch and flight-following procedures that include up-to-date weather information and assistance in flight risk assessment decisions; and to implement a flight risk evaluation program.[28]

C. Safety-Enhancing Technology

Many safety-enhancing technologies are being discussed as ways to improve HEMS safety and prevent accidents. FAA does not require the use of any of the technologies listed below for HEMS, but has offered guidance for implementation.

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[25] AAMS, AMOA and HAI, Air Medical Service Safety Position Paper (Jan. 13, 2009). Local, regional, county, or state policy, law, and regulation oftentimes determine how this works. Further, many hospitals have protocols of when to request a helicopter and which HEMS operator to contact.

[26] NTSB, *supra* note 10, at 7.

[27] *See* AC 135-14A (1991) and N8000.301 "Operational Risk Assessment Programs for [HEMS]" (2005).

[28] NTSB Recommendations A-06-13 and A-06-14 (2006).

Radar Altimeters show a pilot how high the aircraft is above the ground to assist the pilot in maintaining ground clearance. According to the NTSB, radar altimeters can increase altitude awareness to help prevent inadvertent descent below set height during hovering operations and low-altitude cruise flight, and can alert a pilot (visually and/or aurally) when the helicopter approaches and then descends below a preselected altitude.[29] Radar altimeters can prevent controlled flight into terrain (CFIT) accidents,[30] which involves the pilot losing situational awareness. In 2007, the NTSB recommended that FAA should require HEMS operators to install radar altimeters in all helicopters used in night operations and require that they be operable.[31] The FAA issued notices to aviation safety inspectors to emphasize pilot and flight crew knowledge of equipment, including radar altimeters;[32] and to encourage HEMS operators to use radar altimeters in night operations.[33] According to the FAA, the equipage and use of radar altimeters will be addressed in an upcoming rulemaking project.

Helicopter Terrain Awareness and Warning Systems (HTAWS), also known as Enhanced Ground Proximity Warning Systems (EGPWS), is another technology that can prevent CFIT by providing terrain and obstacle aural and visual alerts to pilots. The technology:

> [u]ses aircraft inputs such as position, attitude, air speed and glideslope, which along with internal terrain, obstacles, and airport databases predict a potential conflict between the aircraft's flight path and terrain or an obstacle. . . . When coupled with display, the surrounding terrain can be viewed relative to the aircraft position.[34]

According to the NTSB, HTAWS "can substantially reduce pilot workload and improve the margin of safety during limited visibility conditions, which are often encountered during EMS operations." The NTSB recommended that FAA require operators to have HTAWS in aircraft and to provide adequate training to ensure that flight crews are capable of using the systems.[35] In December 2008, FAA established the manufacturing standards for HTAWS. According to the FAA, current market costs for HTAWS is approximately $16,000 to $120,000 per helicopter.

Night Vision Imaging Systems (NVIS)/Night Vision Goggles (NVG) enhance a pilot's vision at night by capturing ambient light and providing pilots/crew with a monochrome visual field. NVIS enhance a pilot's situational awareness and reduce pilot workload and stress.[36] NVG allow pilots to see trees, poles and towers that may not be detected by the naked eye or other technologies like HTAWS. After an operator purchases the NVG, the entire interior helicopter

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[29] Letter from Mark V. Rosenker, Chairman, NTSB, to Robert A. Sturgell, Acting Administrator, FAA (Dec. 21, 2007).
[30] One example of a CFIT accident was the LifeNet, Inc. helicopter air ambulance that crashed into the Potomac River near Oxen Hill, Maryland on Jan. 10, 2005. *See* NTSB Accident Brief NTSB/AAB-07/04.
[31] NTSB Recommendations A-07-111 and A-07-112. The operability requirement would raise the priority level on maintenance checklists should the radar altimeter become inoperable.
[32] Notice N8000.307, Special Emphasis Inspection Program for [HEMS] (Sept. 27, 2005).
[33] Notice N8000.293, [HEMS] Operations (Jan. 28, 2005). The information from that Notice was reissued in a Safety Alert for Operators (SAFO) #06001 on January 28, 2006.
[34] Honeywell - http://www51.honeywell.com/aero/Products-Services/Avionics-Electronics/Egpws-Home3/Products.html?c=21.
[35] NTSB Recommendation A-06-15 (Jan. 25, 2006) was added to its 2009 Most Wanted List. FAA reports that requiring HTAWS will be part of its upcoming rulemaking on HEMS.
[36] W.T. Sampson, G.B. Simpson, and D.L. Green, FAA, [NVG] in EMS Helicopter (1994).

cockpit display and lighting must undergo modifications to be compatible with the NVG.[37] Flight crew must also receive training on how to use the NVG. Current estimates for the NVG are about $7,000 per pair, however FAA estimates that the cockpit retrofit and training can cost up to $100,000 per helicopter. It is estimated that 49 percent of HEMS accidents occur on night missions, while only 36 percent of missions occur at night.[38]

Flight data recorders (FDR) and **cockpit voice recorders (CVR)** are usually large and heavy devices used in airplanes and some helicopters. CVRs are required in helicopters that have a seating configuration for 6 or more passengers or for which two plots are required. Both devices can assist accident investigators by providing information on aircraft system status, flight path and attitude; and understand conditions and events leading up to the crash or other safety incidents.[39] New, smaller devices that perform the function of traditional FDR and CVR have been developed for helicopters and some HEMS operators have installed them voluntarily. The FAA has not issued manufacturing and design specifications for these smaller devices, many of which are the size of a cellular phone. Other devices are being developed and/or are in use, such as cockpit image recorders, which include camera and video images.[40]

Other safety technologies can enhance pilots' situational awareness, and assist in terrain, obstacle and weather avoidance, including GPS, ADS-B, Synthetic Vision Systems (which uses an onboard digital map of terrain, obstructions, and buildings[41]), Traffic Collision Avoidance Systems, Electronic Flight Bags and Moving Map Displays. Additional safety discussions have focused on whether helicopter air ambulances should be multi-engine instead of single-engine (commonly used today). As with any technological improvement, technology equipage depends on which investments will provide the most significant safety improvements.

D. Pilot Training

Eighty-four percent of fatal HEMS accidents may be associated with human error.[42] As such, recent safety emphasis has been directed towards HEMS pilot training. Currently, the FAA does not require a standard HEMS pilot training program. However, FAA has offered guidance to operators to assist them in creating training programs.[43] It is reported that pilot training programs include areas such as adverse weather operations, risk assessment programs, night and low visibility conditions, CFIT avoidance, recovery from inadvertent flight into instrument meteorological conditions (IMC)—which is inadvertently entering instrument conditions while under VFR, safe altitude training, loss of control, weather analysis, and simulation training with medical personnel.[44] Most HEMS operators provide initial, recurrent, and transition flight and ground training. One pilot group has recommended that pilots be trained on a flight simulation training device (FTD). Additionally, many discussions have focused on whether safety data suggests that HEMS operators should use a two-pilot operation to enhance safety.

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[37] International Traffic in Arms Regulations (ITAR) prevents operators from purchasing helicopters with NVG-compatible cockpit displays; therefore, retrofitting must be done after.

[38] Blumen, *supra* note 6, at 25.

[39] FAA, http://www.faa.gov/news/fact_sheets/news_story.cfm?newsId=6763

[40] *See* NTSB Recommendation A-00-30 (April 11, 2000).

[41] FAA, Review of Helicopter EMS Accidents and the Effectiveness of Selected Interventions (2009).

[42] Blumen, *supra* note 14, at ii.

[43] *See* FAA Notices 8000.293, 8000.301, 8000.307.

[44] National EMS Pilots Association, Position Statement Prepared for NTSB Hearing, at 13-16.

Since HEMS medical crew often assists pilots, attention has focused on Crew Resource Management (CRM) training. The philosophy of CRM is to train pilots, medical crew, and ground personnel together to provide an environment with open communication and mutual understanding. CRM for HEMS can also allow pilots and medical crew to better understand each others' roles and responsibilities, and reduce stress.[45] However, some point to risks associated with pilot and medical crew interaction that could distract pilots from flight duties or inappropriately heighten a pilot's sense of exigency in a situation, which could affect his/her critical decision making.

E. Fatigue

Fatigue in aviation can pose a serious threat to pilot and crew performance. While there has not been a formal study on fatigue in the HEMS environment, many of the known threats of fatigue remain, such as sleep inertia, circadian rhythm interruption, sleep debt, chronic and acute fatigue, and alertness. Many suspect that fatigue may be contributing to HEMS accidents. HEMS pilots work demanding, and oftentimes erratic, schedules that alternate between long day or night shifts, followed by required rest periods.

Under FAA's part 91 regulations, there are no formal flight and duty time requirements. Under part 135, the flight crew must have adequate rest, with a maximum duty time of 14 hours; flight time may not exceed 8 hours during any 24-consecutive hour period. This potentially means that if the flight crew had already reached a maximum of 14 hours and had just dropped off a patient under part 135, it could still return the helicopter to the base without a patient on board under part 91, putting total duty time well over 14 hours. According to the NTSB, "This situation could result in a pilot flying in a fatigued condition during the Part 91 leg of the flight or not getting adequate rest during his time off, leaving him fatigued when he returns to duty."[46] NTSB also noted that the pilot's hours flown under part 91 do not count towards the pilot's total duty time under part 135.[47]

F. HEMS Inspections

GAO's 2007 report was critical of FAA's existing inspections approach and resources allocated to address HEMS operations. HEMS operators receive a minimum number of inspection hours according to the FAA's National Flight Standards Work Program Guidelines; and principal inspectors determine if additional inspection hours are needed to ensure adequate oversight depending on the size and risk factors of the operator. Further, GAO noted that FAA needs inspectors that are trained to certify safety technologies that are being installed on helicopter air ambulances. GAO has also pointed out that FAA had difficulty with inspecting HEMS operators at remote helicopter air ambulance base locations. FAA principal inspectors may not have adequate time or travel funds to visit these locations. As such, inspectors located in the geographic area of a HEMS base, who may not have the same level of training, are often used to assist with remote base inspections.[48] To assist with some of these issues, FAA established HEMS-specific Aviation Safety

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[45] Blumen, *supra* note 14, at 51-52.
[46] NTSB, *supra* note 10, at 2. *See* NTSB Safety Recommendations A-94-194 and A-95-113 regarding fatigue–both are "Open—Unacceptable Response."
[47] Section 816 of H.R. 915, requires the FAA to conduct a rulemaking to require that all flight time under part 91 be included in a flight crewmember's total flight time limitations under part 135.
[48] GAO, *supra* note 5, at 29-30.

Inspectors (ASIs) in August 2006; there are currently 42 ASIs dedicated to HEMS operators. According to the FAA, it has authorized an increase of additional 19 to be added in fiscal year 2009.

G. H.R. 1201

The Air Medical Safety Act, H.R. 1201, introduced by Rep. Salazar and Rep. Lungren, would require: operators to conduct all operations under part 135 regulations on all legs of a trip; FAA to develop consistent flight dispatch procedures; and FAA to undertake rulemakings to develop a flight risk evaluation program and to require FDR and CVR functional devices onboard EMS aircraft.

II. State Regulation of HEMS

A. State Regulations

When the Airline Deregulation Act[49] (ADA) was enacted in 1978, it removed government control from air carriers' rates, routes, and services, and sought to make it easier for new entrant air carriers to enter into the domestic market. The ADA state preemption provisions were a controversial part of the deregulation debate, with several states arguing they should be allowed to continue to regulate intrastate air carriers. The airlines argued that they could not compete fairly or operate efficiently in an aviation environment with multiple sets of rules and regulations.[50] At this time, the HEMS industry was just emerging; therefore, the issues relating to it were not explored explicitly in the ADA. Since 1978, courts have maintained that the ADA preempts state regulation of aviation,[51] but that states retain the right to regulate medical aspects of HEMS operations.

Though states are prohibited from regulating air carrier rates, routes, or services, they have the authority to regulate medical care. For example, many states dictate HEMS requirements for the medical training and qualifications of healthcare professionals onboard aircraft. States may also regulate performance standards for aircraft cabin temperature, helicopter equipment used to communicate with EMS officials on the ground, compliance with medically-dictated pickup and drop-off protocols, sanitary conditions onboard the helicopter, require a plan for upkeep of medical equipment, and medically mandated design of air ambulance bays (consistent with FAA safety rules).[52] However, the FAA retains safety oversight. For example, if a state requires air ambulances to carry a minimum amount of oxygen, the FAA identifies the location and method of oxygen canister installation; if a state mandates 75 degree temperature in the passenger bay, the FAA specifies the size or type of heating/cooling systems; and if a state requires a defibrillator, the FAA determines methods for securing the defibrillator when it is not in use.

Some states have established Certificate of Need (CON) programs, which are written to keep the price of healthcare low. A CON is a planning tool used by states to prevent excessive healthcare services, leading to healthcare price inflation.[53] States issue a CON based on a community's need for services. Some have said that CONs are a way for states to regulate entry,

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[49] Airline Deregulation Act of 1978, Pub. L. No. 95-504 (1978) (codified as amended at 49 U.S.C. § 41713 (2008)).
[50] John Fischer, CRS, Issues Relating to the Regulation of Air Ambulance Services, 2 (2008).
[51] See e.g. *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 378-9 (1992).
[52] DOT, Air Ambulance Briefing, Briefing to Congressional staff (Mar. 27, 2009) at 7.
[53] National Conference of State Legislatures, Certificate of Need: State Health Laws and Programs, (reposted Feb. 13, 2009), http://www.ncsl.org/programs/health/cert-need.htm.

coverage, and scope of services, for HEMS operators. When a state has a CON program for HEMS, a HEMS operator trying to enter that market must demonstrate that the existing HEMS services in that area are insufficient to accommodate the need. Most often, if a state has a HEMS CON, HEMS operators may not transport patients without a license in that state. In addition to setting a limit on the number of HEMS operators, some CON laws set very specific equipment requirements. Some have voiced concern over whether or not states have the expertise in aviation to justify such state requirements. Fewer than 10 states have a CON program for HEMS operators.[54] Some claim that a HEMS CON gives states the resources to control growth in air medical services. Others claim that allowing CON regulations may create "borders in the sky" with each state having its own specific regulatory scheme, limiting HEMS services across state lines.

B. Legal Issues Regarding State Regulation of HEMS

In response to requests, the DOT interprets the ADA through "letters of opinion." DOT provides a determination of whether a state regulation pertaining to an air carrier (including helicopter air ambulances) is preempted by the ADA. The DOT has found that particular state regulations regarding HEMS went beyond regulating the medical aspects within the state's jurisdiction and were preempted by the ADA with respect to rates, routes, and services. For example, the DOT has issued opinions on a states' use of a CON program or public necessity and convenience (PC&N) requirements,[55] rate setting, limitation on geographic service areas (mandating that air carriers service specific areas), and 24-hour/7-day availability.

In 2007, Med-Trans Corp., a multi-state HEMS operator interested in operating in North Carolina, asked DOT to give guidance on whether North Carolina's CON requirement for HEMS operators enforced a stipulation of law that related to rates, routes, and services. In a November 13, 2007 letter, DOT concluded that "North Carolina's CON requirements are ones that relate to the routes and services of an air carrier, and as such are preempted." DOT further stated that "the North Carolina requirement directly encroaches on the pro-competitive Federal scheme mandated by Congress and is prohibited by section 41713 [Title 49 U.S.C. § 41713 -- ADA]."[56]

Med-Trans went on to challenge North Carolina's HEMS laws in court. The U.S. District Court for the Eastern District of North Carolina found that many, though not all, of the State's laws regarding HEMS were preempted by the ADA. The court rejected State regulations that required a CON, mandated participation in an EMS Peer Review Committee, and required operators to have 24-hour/7 day-a-week availability.[57] The court ruled that since the collective economic effect of the regulatory system pertaining to medical oversight could be used to prevent an air carrier from operating at all within the State, those laws are preempted by the ADA. The court stated that medical oversight is within the State's authority to regulate, provided that the State laws do not conflict with federal law. However, the court found that medical functions within the State's HEMS regulatory authority include: requiring an air ambulance provider to synchronize his or her voice radio communications to local emergency service resources, providing documented plans for

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[54] *Id.*

[55] DOT considers a CON and PC&N as equivalent.

[56] Letter from D.J. Gribbin, General Counsel, DOT, to Albert B. Randall, Counsel for Med-Trans Corp., (Nov. 13, 2007).

[57] *Med-Trans Corp. v. Benton*, 581 F. Supp. 2d 721 (E.D.N.C. 2008).

transporting patients to appropriate medical facilities in the event of a diversion or bypass, and mandating medical equipment that can be reasonably detached from the aircraft safely.

In 2007, Pacific Wings L.L.C. requested a DOT opinion of Hawaii's CON program for HEMS operators. DOT investigated Hawaii's CON program, prompting Hawaii's Deputy Attorney General to review and find the CON was preempted by the ADA. As a result, Hawaii withdrew its CON. DOT also found that Hawaii's 24-hour operability requirement encroached on the ADA, but specified that as a customer, a state or local government may opt to contract with or use the services of only those who offer 24-hour service distinguishing the action of a customer from that of a regulator. DOT also found Hawaii's equipment requirements to be outside DOT's scope of regulation, though the letter reiterated that "Hawaii may prescribe such medical supplies and equipment for air ambulance operators, so long as FAA requirements are met regarding how those items are safely installed and carried aboard any aircraft."[58]

In 2008, the Texas Attorney General requested an opinion of whether Texas' "Subscription Programs" are preempted by the ADA. The Texas EMS Subscription Program offers residents of a certain area a membership in its program for an annual fee, members are then not charged or are charged a reduced fee for any emergency medical services and transport to a hospital. The DOT found that Texas subscription rules on advertisement and bonding preempted the ADA, because they are economic regulation of air carriers. DOT offered an alternative to the preempted economic regulation by suggesting that a state focus on "a breach of contract claim against an air ambulance operator for breach of the subscription contract"[59] to accomplish the same goals.

C. H.R. 978

H.R. 978, the "Helicopter Medical Services Patient Safety, Protection, and Coordination Act", introduced by Representative Jason Altmire, amends Title 49 to expand states' authority to regulate HEMS operations, including: medical training of aircraft medical personnel; medical equipment carried on the aircraft; and the communication capabilities enabling the aircraft to communicate with emergency medical services personnel and institutions receiving patients. The bill also includes language that obligates service providers to comply with health planning and medical service requirements, which includes coordinating the transport of patients with emergency medical services, demonstrating a need for new or expanded services, and limitations on the number of aircraft providing services within a state or region of a state. It also proposes to allow states to regulate service requirements with respect to geographic areas or during specified hours and days, and can require operators to comply with certain accreditation requirements.[60] Lastly, the legislation does not change any limitations of state authority with respect to rates, taxes, or user fees of an air carrier.

Supporters of the legislation claim that H.R. 978 simply clarifies state authority to regulate medical care provided in HEMS operations similar to how states regulate ground ambulances. They

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[58] Letter from Rosalind A. Knapp, Acting General Counsel, DOT, to Gregory S. Walden, Counsel for Pacific Wings, L.C.C. (Apr. 23, 2007).

[59] Letter from D.J. Gribbin, General Counsel, DOT, to Honorable Greg Abbott, Texas Attorney General (Nov. 3, 2008).

[60] Many HEMS operators are accredited by the Commission on Accreditation of Medical Transport Systems (CAMTS), which offers voluntary accreditation standards for an operator that can establish a high quality of safety in medical care and transport of patients. Some states require HEMS operators to obtain CAMTS-like accreditation.

state that this legislation sets forth a sphere in which the state is not preempted by the ADA. Supporters also claim that numerous state laws governing HEMS have been undermined by challenges citing federal ADA preemption and that a lack of clarity threatens patient safety, and the quality of patient care, and impedes the proper coordination of services.

Opponents of the legislation contend that H.R. 978 is unnecessary because states already have the authority to regulate medical care. Opponents also assert that, no matter the intent of the legislation, its effect would be fewer HEMS operators, resulting in decreased competition. As such, small and rural communities could experience a decreased presence of operators in their vicinity. Some assert it would ultimately erode federal jurisdiction over the economic and operational aspects of HEMS, and would create the potential for safety conflicts in the national airspace system. Some operators say that the current regulatory scheme allows them to be flexible, enabling them to have a mixture of different helicopters with different equipment, specialized for specific patient needs. Legislation requesting a "carve out" for specific aviation communities has a potential slippery slope effect on the rest of aviation, may create unnecessary complexity in the air ambulance industry, prevent patient transport across state lines, and could limit market entry.

APPENDIX I: RECENT HEMS ACCIDENTS

Date	Location	No. Killed or Injured	Helicopter Type	Description and/or Probable Cause and Contributing Factors[61]	Operator Model	Operating Conditions
Oct. 15, 2008	Aurora, IL	4 fatal	Bell 22	Impacted a radio station tower.	Independent	Part 135 Night
Sept. 27, 2008	District Heights, MD	4 fatal	AS365	Collision with trees and terrain.	Public use	Part 91 Night
Aug. 31, 2008	Greensburg, IN	3 fatal	Bell 206	Collision with terrain and post-impact fire.	Independent	Part 91
June 29, 2008	Flagstaff, AZ	7 fatal	Bell 407 (2)	Pilots' failure to identify and arrest the helicopter's descent, resulting in its impact with terrain. Factors: inadvertent flight into IMC, and limited visual references.	Hospital-based; Independent	Part 135, VFR Night
June 27, 2008	Ash Fork, AZ	Non-fatal; 3 serious	AS350	Collision with terrain during attempted "go-around."	Independent	Part 91 Night
June 8, 2008	Huntsville, TX	4 fatal	Bell 407	Cause: Impact with terrain due to pilot failure to identify and arrest descent. Factors: inadvertent flight into IMC; limited visual reference due to night conditions, low clouds, and fog.	Independent	Part 135, VFR
May 30, 2008	Pottsville, PA	Non-fatal; 3 inj.	EC135	Collision with a semi-trailer, parked at an adjacent loading dock.	Hospital-based	Part 91 Night
May 29, 2008	Grand Rapids, MI	Non-fatal; 2 serious	S76A	Pilot's failure to maintain tail rotor obstacle clearance from a tower during takeoff from hospital.	Hospital-based	Part 91
May 10, 2008	La Crosse, WI	3 fatal	EC135	Collision with trees and terrain.	Hospital-based	Part 91 Night
Feb. 5, 2008	South Padre Island, TX	3 fatal	AS350	Cause: pilot failure to maintain aircraft control resulting helicopter impact with water. Factors: Inadvertent flight into IMC, low ceiling, darkness, and lack of pilot experience.	Hospital-based	Part 91 Night
Dec. 30, 2007	Cherokee, AL	3 fatal	Bell 206	Cause: Pilot's failure to maintain control of the helicopter during its low hover. Factor: Loss of tail rotor effectiveness.	Independent	Part 91 Night
Dec. 3, 2007	Whittier, AK	4 fatal	BK 117	Probable: VFR flight into IMC. Factors: operator's failure to adhere to an FAA-approved and mandated risk management program; pilot's lack of experience in night and winter operations, operators lack of an EMS dispatch and flight following system.	Hospital-based	Part 135, VFR Night

[61] Probable cause and contributing factors are determined by the NTSB following its complete investigation.

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